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EXAMINER

SANDALS, WILLIAM O

ART UNIT PAPER NUMBER

1636

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/736,632

Applicant(s)

Baker

Examiner  
William Sandals

Art Unit  
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 18, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 38-68 is/are pending in the application.
- 4a) Of the above, claim(s) 1-24 and 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-34 and 42-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 6) ☐ Other:

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**DETAILED ACTION**

***Election/Restriction***

1. Claims 1-24 and 38-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups I and III, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7, filed April 25, 2002.
2. Applicant's election without traverse of Group I, claims 25-37, species BIS-TRIS in Paper No. 7 is acknowledged.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 contains the trademark/trade name PCR. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark

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or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polymerase chain reaction and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 25, 27-31, 34, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Peterson et al., Reeck et al. and Kothari et al.

Each of Peterson et al. (see especially "experimental procedures") , Reeck et al. (see especially pages 2317 and 2318) and Kothari et al. (see the entire article) taught a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample, comprising a plurality of positively ionizable groups consisting of a biological buffer where the biological buffer is TRIS (called ECTHAM). The ionizable groups are immobilized on a solid support by covalent bonds.

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7. Claims 25, 26, 35 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by the Sigma catalogue.

The Sigma catalogue teaches (pages 1556-1560) a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample, comprising a plurality of positively ionizable groups consisting of a biological buffer.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 25, 27-31, 34, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,843,663.

US 5,843,663 (see especially columns 1 and 2) taught a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample, comprising a plurality of positively ionizable groups consisting of a polyhydroxylated amines, histidine and polyhistidine. The ionizable groups are immobilized on a solid support by covalent bonds.

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***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 25-31 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. in view of Reeck et al., Kothari et al. and the Sigma catalogue.

The claims are drawn to a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample, comprising a plurality of positively ionizable groups consisting of a biological buffer where the elected species is BIS TRIS. The ionizable groups may be immobilized on a solid support by covalent or ionic bonds or by adsorption.

Each of Peterson et al., Reeck et al., Kothari et al. and the Sigma catalogue taught the invention as described above in the rejection under 35 USC 102. Each of Peterson et al., Reeck et al., Kothari et al. teach that the buffer was TRIS (called ECTHAM). Each of Peterson et al., Reeck et al., Kothari et al. teach a solid phase product used in a method of isolating nucleic acids where Reeck et al. and Kothari et al. states that the solid phase product is a weak ion exchanger.

Kothari et al. taught the use of many solid phase and water soluble products including the biological buffer TRIS (called ECTHAM) which comprised ionizable groups and which were bound to a solid support for use in a method of isolating nucleic acids.

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Each of Peterson et al., Reeck et al. and Kothari et al. did not teach the biological buffer BIS TRIS and the Sigma catalogue did not teach the immobilization of BIS TRIS to a solid surface.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Peterson et al. with Reeck et al., Kothari et al. and the Sigma catalogue because they each taught the use of the immobilized biological buffer TRIS which provided positively ionizable groups for the isolation of nucleic acids. Reeck et al. taught at page 2318, column 2, last paragraph, that the weak ionization properties of the immobilized TRIS buffer was ideally suited for nucleic acid isolation. The teachings of Kothari et al. extend the teaching of Reeck et al. to a broad class of compounds which all share the property of weak ionization, making them suited for isolation of nucleic acids. The breadth of teachings of Kothari et al. and Reeck et al. makes it obvious to one of ordinary skill in the art that the BIS TRIS biological buffer taught by the Sigma catalogue which shares the weak ionization properties of TRIS would therefore be ideally suited to isolation of nucleic acids when immobilized on a solid surface. Kothari et al. and Peterson et al. provide the teachings for binding the biological buffer TRIS to a solid support. The instant claimed BIS TRIS biological buffer bound to a solid support for isolation of nucleic acids would be an obvious choice to one of skill in the art because the weak ionization properties of BIS TRIS is taught by the Sigma catalogue as is the TRIS buffer of each of Peterson et al., Reeck et al. and Kothari et al.

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One of ordinary skill in the art would have been motivated to combine the teachings of Peterson et al. with Reeck et al., Kothari et al. and the Sigma catalogue because Reeck et al. teach at page 2318, column 2, last paragraph, the useful and desirable weak ion-exchanger produced by binding a biological buffer such as TRIS to a solid support to isolate nucleic acids from a sample comprising nucleic acids. Kothari et al. also teach the useful and desirable isolation of nucleic acids from a sample with a solid phase product made by binding weakly ionizing compounds such as biological buffers to a solid support. The Sigma catalogue teaches a large number of species of biological buffers which are weakly ionizing, all of which are suitable for use in a method of isolation of nucleic acids as taught by each of Peterson et al., Reeck et al. and Kothari et al. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Peterson et al. in view of Reeck et al., Kothari et al. and the Sigma catalogue.

11. Claims 25-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. in view of Reeck et al., Kothari et al. and the Sigma catalogue as applied to claims 25-31 and 34-37 above, and further in view of US 5,874,221 and US 5,916,746.

The claims are as described above and also to a product which is a container which may be a PCR or storage tube or well or a pipette tip.

Each of Peterson et al., Reeck et al., Kothari et al. and the Sigma catalogue taught the invention as described above.



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Each of Peterson et al., Reeck et al., Kothari et al. and the Sigma catalogue did not teach a product which is a container which may be a PCR or storage tube or well or a pipette tip.

US 5,916,746 taught (see especially column 6, lines 21-58) a solid support which is a ion exchanger with ionizable groups where the solid support is in the form of a tube of a multiwell plate which can be used in a method of isolation of nucleic acids or in a method of polymerase chain reaction.

US 5,874,221 taught (see especially column 14) the isolation of nucleic acids in an ion exchange pipet tip which may be used to isolate nucleic acids for use in a polymerase chain reaction.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Peterson et al., Reeck et al., Kothari et al. and the Sigma catalogue with US 5,874,221 and US 5,916,746 because US 5,874,221 or US 5,916,746 teach an ion exchanger which is in the form of a tube or well or pipette, where the ion exchanger is used in a method of isolation of nucleic acids and in a method of polymerase chain reaction.

One of ordinary skill in the art would have been motivated to combine the teachings of Peterson et al., Reeck et al., Kothari et al. and the Sigma catalogue with US 5,874,221 and US 5,916,746 because US 5,874,221 or US 5,916,746 teach that an ion exchanger which is in the form of a tube or well or pipet is useful and desirable in a method of isolation of nucleic acids with an ion exchanger to reduce the number of manipulations of a sample in the method or to reduce the time required for the isolation method. Further, a person of ordinary skill in the art

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would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Peterson et al., Reeck et al., Kothari et al. and the Sigma catalogue with US 5,874,221 and US 5,916,746.

### *Conclusion*

12. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

June 14, 2002



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## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-34 and 38-68 are pending in the application. Claims 35-37 have been cancelled in Paper No. 10, filed December 18, 2002. Claims 1-24 and 38-41 are withdrawn from examination.
2. Amendments to the claims in Paper No. 10 have overcome the rejection of claim 33 under 35 USC 112, second paragraph in the previous office action, and the rejection is withdrawn.
3. Amendments to the claims in Paper No. 10 have overcome the rejection of claim 25, 26 and 35 under 35 USC 102 over the Sigma catalogue in the previous office action, and the rejection is withdrawn.
4. Amendments to the claims in Paper No. 10 have overcome the rejection of claim 25, 27-31, 34, 36 and 37 under 35 USC 102 over US 5,843,663 in the previous office action, and the rejection is withdrawn.
5. Claims 25-34 and 42-66 stand rejected under 35 USC 112, second paragraph, under new grounds of rejection below.
6. Claims 25, 27, 34, 42, 44, 48 and 66 stand rejected under 35 USC 102(b) as being anticipated over Peterson et al., Reeck et al. and Kothari et al. The response to the arguments is contained in the rejection repeated below.

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7. Claims 25-27, 34, 42-44, 48, 51, 52 and 66 stand rejected under 35 USC 102(e) as being anticipated over Burton et al., under new grounds of rejection below.
8. Claims 25-27, 34, 42-44, 48, 51, 52, 56 and 66 stand rejected under 35 USC 103(a). The response to the arguments is contained in the rejection repeated below.
9. This application contains claims 1-24 and 38-41, drawn to an invention nonelected without traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

*Response to Arguments*

11. The following rejections are repeated from the previous office action.

*Claim Rejections - 35 USC § 102*

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 25, 27, 34, 42, 44, 48 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al.

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Peterson et al. teaches at the section entitled "experimental procedures", a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample. The solid phase product (called ECTHAM) of Peterson et al. consists of a plurality of positively ionizable groups which are from a biological buffer TRIS. The ionizable groups are immobilized on solid support cellulose beads by covalent bonds (as recited in instant claims 27, 48 and 66)(see the section in Peterson et al. at the bottom of page 2916, column 2, bridging to page 2917, entitled "Preparation of ECTHAM-Cellulose"). TRIS buffer is a notoriously well known water soluble biological buffer. ECTHAM has the inherent property of binding nucleic acids at a lower pH and releasing nucleic acids at a higher pH as taught by Reeck et al. in the rejection under 35 USC 102(b) below.

14. Claims 25, 27, 34, 42, 44, 48 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Reeck et al.

Reeck et al. teaches at pages 2317 and 2318 the use of ECTHAM, a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample. The solid phase product (called ECTHAM, as taught above in the rejection of claims 25, 27, 34, 42, 44, 48 and 66 under 35 USC 102(b) over Peterson et al.) consists of a plurality of positively ionizable groups which are from a biological buffer TRIS. The ionizable groups are immobilized on solid support cellulose beads by covalent bonds (as recited in instant claims 27, 48 and 66). TRIS buffer is a notoriously well known water soluble biological buffer. ECTHAM has the inherent

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property of binding nucleic acids at a lower pH and releasing nucleic acids at a higher pH as demonstrated in the teachings of Reeck et al. at Figure 1.

15. Claims 25, 27, 34, 42, 44, 48 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Peterson et al., Reeck et al. and Kothari et al.

Kothari et al. teach at the introduction and page 454, the use of ECTHAM, a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample. The solid phase product (called ECTHAM, as taught above in the rejection of claims 25, 27, 34, 42, 44, 48 and 66 under 35 USC 102(b) over Peterson et al.) consists of a plurality of positively ionizable groups which are from a biological buffer TRIS. The ionizable groups are immobilized on solid support cellulose beads by covalent bonds (as recited in instant claims 27, 48 and 66). TRIS buffer is a notoriously well known water soluble biological buffer. ECTHAM has the inherent property of binding nucleic acids at a lower pH and releasing nucleic acids at a higher pH as taught by Reeck et al. in the rejection under 35 USC 102(b) above.

16. Each of Peterson et al., Reeck et al. and Kothari et al. teach the use of ECTHAM in a method of immobilizing and releasing nucleic acids. The arguments presented by Applicants below are directed to the nature of the polymer ECTHAM. Therefore, the rebuttal to these arguments which follows below, applies to each of Peterson et al., Reeck et al. and Kothari et al.

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17. In response to the rejection of claims 25, 27, 34, 42, 44, 48 and 66 under 35 U.S.C. 102(b) as being anticipated by each of Peterson et al., Reeck et al. and Kothari et al. in Paper No. 11 page 21, Applicants argue that the teachings of Peterson et al., Reeck et al. and Kothari et al. do not include the use of the immobilized TRIS in a "charge switching" method, and at page 22, lines 20-23 of Paper No. 11 state "[i]t is believed that the chemical reactions involved in producing ECTHAM Cellulose do not yield a material having the charge switch characteristic of the solid phase product claimed by applicant herein".

The teachings of Peterson et al., Reeck et al. and Kothari et al. all recite the use of ECTHAM, which is TRIS which has been immobilized on a cellulose solid support. While applicants do not believe that ECTHAM has the charge switch characteristics of the instant claimed solid phase product, no evidence to support this assertion has been presented. As a consequence, the argument is not found convincing. Further, Figure 1 of Reeck et al. teaches the elution of the sonicated chromatin from a column of ECTHAM by a pH gradient. This teaching clearly indicates the ability of ECTHAM to operate with a charge switch character. The claimed property of the instant claimed solid phase product is thus inherent in the ECTHAM as taught by Peterson et al., Reeck et al. and Kothari et al. Therefore, lacking evidence to the contrary, the arguments are not found convincing.

18. In response to the rejection of claims 25, 27, 34, 42, 44, 48 and 66 under 35 U.S.C. 102(b) as being anticipated by each of Peterson et al., Reeck et al. and Kothari et al. in Paper No. 11 page 23, lines 1-9, Applicants argue that the teachings of Peterson et al., Reeck et al. and

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Kothari et al. are directed to the use of ECTHAM as an ion exchanger, not in a charge switch character.

As noted above, Reeck et al. teach the use of ECTHAM in a charge switch character. The argument is therefore, not found convincing.

19. In response to the rejection of claims 25, 27, 34, 42, 44, 48 and 66 under 35 U.S.C. 102(b) as being anticipated by each of Peterson et al., Reeck et al. and Kothari et al., Applicants argue in Paper No. 11 page 22 line 14 bridging to page 23, line 9, that none of Peterson et al., Reeck et al. and Kothari et al. teach the water soluble product of claim 34 which is "separately attached" to a polymer.

On the contrary, ECTHAM is comprised of TRIS buffer which is covalently, and separately attached to a cellulose polymer. TRIS buffer is well known to be a water soluble buffer. Therefore, these limitations of the claim are met, and the argument is not found convincing.

### ***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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21. Claims 25-27, 34, 42-44, 48, 51, 52, 56 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Peterson et al., Reeck et al., Kothari et al. and Burton et al. in view of the Sigma catalogue.

The claims are drawn to a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample, comprising a plurality of positively ionizable groups consisting of a biological buffer where the elected species is BIS TRIS. The ionizable groups may be immobilized on a solid support by covalent or ionic bonds or by adsorption.

Each of Peterson et al., Reeck et al., Kothari et al. and Burton et al. teach a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample, comprising a plurality of positively ionizable groups consisting of a biological buffer where the elected species is BIS TRIS. The ionizable groups may be immobilized on a solid support by covalent or ionic bonds or by adsorption. invention as described above in the rejection under 35 USC 102. Each of Peterson et al., Reeck et al., Kothari et al. teach that the buffer was TRIS (called ECTHAM). Each of Peterson et al., Reeck et al., Kothari et al. teach a solid phase product used in a method of isolating nucleic acids where Reeck et al. and Kothari et al. states that the solid phase product is a weak ion exchanger.

Kothari et al. taught the use of many solid phase and water soluble products including the biological buffer TRIS bound to cellulose in a product called ECTHAM, which comprised the ionizable groups of TRIS buffer, which were bound to the cellulose solid support for use in a method of isolating nucleic acids.

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Each of Peterson et al., Reeck et al., Kothari et al. and Burton et al. did not teach a solid phase product comprising the biological buffer BIS TRIS.

The Sigma catalogue teaches TRIS and BIS TRIS as biological buffers which are equivalent weak ionic compounds, where BIS TRIS has a pH buffering range which overlaps and extends beyond the pH buffering range of TRIS.

BIS TRIS and TRIS buffers are listed in the instant claims in a Markush group of recognized equivalents.

Each of Peterson et al., Reeck et al., Kothari et al. and Burton et al. teach a solid phase product which is water soluble bound to a solid phase support, for use in a method of extracting nucleic acid from a sample, where the solid phase product bound to the solid phase support comprises a plurality of covalently bound, positively ionizable groups. It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to combine the teachings of each of Peterson et al., Reeck et al., Kothari et al. and Burton et al. with the teachings of the Sigma catalogue because the Sigma catalogue teaches the biological buffers TRIS and BIS TRIS which are recognized equivalent biological buffers which share weak ionization properties. The use of TRIS, or BIS TRIS in the alternative, would therefore be ideally suited to isolation of nucleic acids when immobilized on a solid surface. One of ordinary skill in the art would have been motivated to modify the solid phase product of Peterson et al., Reeck et al., Kothari et al. and Burton et al. with the equivalent BIS TRIS biological buffer as taught by the Sigma catalogue for the expected benefit of extending the pH range of ionization in

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a method of immobilizing nucleic acids. Reeck et al. teach at page 2318, column 2, last paragraph, that ECTHAM is highly desirable to isolate nucleic acids from a sample comprising nucleic acids. Kothari et al. teach at the introduction, page 449, that the modification of cellulose with functional groups appreciably increases retention of nucleic acids from a sample. The functional groups of ECTHAM are TRIS molecules, covalently coupled to cellulose beads to form a solid phase product with weakly ionizing functional groups. The Sigma catalogue teaches a large number of species of biological buffers which are weakly ionizing, all of which are suitable for use in a method of isolation of nucleic acids as taught by each of Peterson et al., Reeck et al. and Kothari et al. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Peterson et al., Reeck et al., Kothari et al. and Burton et al. and the Sigma catalogue.

22. Claims 25-31, 34 and 42-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. in view of Reeck et al., Kothari et al. and the Sigma catalogue as applied to claims 25-27, 34, 42-44, 48, 51, 52, 56 and 66 above, and further in view of US 5,599,667 (Arnold, Jr. et al.), US 5,5512,439 (Hornes et al.) and US 6,060,246 (Summerton et al.).

The claims are drawn as described above, and where the ionizable groups are polymerized, and the solid phase may be beads, which may be magnetic or paramagnetic beads.

Peterson et al., Reeck et al., Kothari et al. and the Sigma catalogue teach the invention as described above.

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Peterson et al., Reeck et al., Kothari et al. and the Sigma catalogue did not teach that the ionizable groups are polymerized, nor that the solid phase may be beads, which may be magnetic or paramagnetic beads.

Arnold, Jr. et al. teach at the abstract, summary, column 8, line 56 bridging to column 9, line 52 and examples 1-3 a solid phase product with ionizable groups attached directly or attached via a polymer spacer to a solid phase support. The solid support may be magnetic beads (see especially examples 1-3). The solid phase product is used for binding and releasing nucleic acids (see especially examples 1-3).

Summerton et al. teach at the summary, column 5, line 61 bridging to column 6, line 51 a solid phase product with amine ionizable groups attached either directly or via a polymer spacer to a solid phase support (see especially column 5, line 61 bridging to column 6, line 51). The ionizable groups bind nucleic acid at a lower pH and release the nucleic acids at a higher pH (see especially column 5, line 61 bridging to column 6, line 51).

Hornes et al. teach at the summary the advantages of using paramagnetic beads over the use of magnetic beads for the binding and release of nucleic acids.

Each of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue with Arnold, Jr. et al., Hornes et al. and Summerton et al. teach a solid phase product for the isolation of nucleic acids by binding to ionizable groups on a solid support. It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to combine the teachings of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue with the teachings of Arnold, Jr.

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et al., Hornes et al. and Summerton et al. they each teach the isolation of nucleic acids by binding to ionizable groups on a solid support. One of ordinary skill in the art would have been motivated to modify the solid phase product for the isolation of nucleic acids by binding to ionizable groups on a solid support of Peterson et al., Reeck et al., Kothari et al., and the Sigma catalogue with the teachings of Arnold, Jr. et al., Hornes et al. and Summerton et al. because Arnold, Jr. et al. teach at column 3, lines 28-34, the expected benefit that the use of magnetic beads will improve the handling and speed of assays for isolation and analysis of nucleic acids. Summerton et al. teach at column 2, lines 11-16 the expected benefit of the use of ionizable amine groups bound to a solid phase support for the rapid isolation and detection of nucleic acids in a polynucleotide-containing sample. Hornes et al. teach at column 1, lines 37-45, the expected benefit of the use of paramagnetic beads to improve handling of the beads, and improve the quantitative isolation and analysis of nucleic acids. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al. and Summerton et al.

23. Claims 25-34 and 42-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al. and Summerton et al. as applied to claims 25-31, 34 and 42-68 above, and further in view of US 5,874,221 (Tooley et al.) and US 5,916,746 (Cobbs et al.).

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The claims are as described above and also to a product which is a container which may be a PCR or storage tube or well or a pipette tip.

Each of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al. and Summerton et al. teach the invention as described above.

Each of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al. and Summerton et al. did not teach a product which is a container which may be a PCR or storage tube or well, or a pipette tip.

Cobbs et al. teach (see especially column 6, lines 21-58) a solid support which is a ion exchanger with ionizable groups where the solid support is in the form of a tube or a multiwell plate. The ionizable groups attached to the solid support are used in a method of isolation of nucleic acids or in a method of nucleic acid amplification by polymerase chain reaction.

Tooley et al. teach (see especially column 14) the isolation of nucleic acids in an ion exchange pipet tip which may be used to isolate nucleic acids for use in a polymerase chain reaction.

Each of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al., Summerton et al., Tooley et al. and Cobbs et al. teach ionizable groups attached to a solid support which is used in a method of isolation of nucleic acids. It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to combine the ionizable groups attached to a solid support which is used in a method of isolation of nucleic acids of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes

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et al. and Summerton et al. with Tooley et al. and Cobbs et al. because each of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al., Summerton et al., Tooley et al. and Cobbs et al. teach ionizable groups attached to a solid support which is used in a method of isolation of nucleic acids. One of ordinary skill in the art would have been motivated to modify the ionizable groups attached to a solid support which is used in a method of isolation of nucleic acids of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al. and Summerton et al. with the nucleic acid binding pipet tip of Tooley et al. for the expected benefit as taught in Tooley et al. at column 14 isolation of nucleic acids a pipet tip eliminates steps in the method of isolation of nucleic acids. when attached to a solid support which is a tube, a multiwell plate, or pipet in a method of isolation of nucleic acids to reduce the number of manipulations of a sample in the method or to reduce the time required for the isolation of the nucleic acids in the method. One of ordinary skill in the art would have been motivated to modify the ionizable groups attached to a solid support which is used in a method of isolation of nucleic acids of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al. and Summerton et al. with the nucleic acid binding tube or multiwell plate of Cobbs et al. for the expected benefit of improving the speed, reducing the number of steps in the method, thereby simplifying the method, improving yield and eliminating sources of handling errors. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al.,

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Hornes et al., Summerton et al., Tooley et al. and Cobbs et al. for production of a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample.

24. In response to the rejection of claims 25-27, 34, 42-44, 48, 51, 52, 56 and 66 under 35 U.S.C. 103(a) as being obvious over each of Peterson et al., Reeck et al. and Kothari et al., Applicants argue in Paper No. 11 page 27 lines 12-18, assert that Kothari et al. at pages 455 et seq. that ECTHAM is inapplicable to the instant claimed invention because these cited teachings are directed to sequence specific binding to the solid phase product.

Kothari et al. at page 455 et seq. do not discuss ECTHAM. The teachings of these cited pages are directed to other means of nucleic acid binding. The argument is therefore not found convincing.

25. In response to the rejection of claims 25-27, 34, 42-44, 48, 51, 52, 56 and 66 under 35 U.S.C. 103(a) as being obvious over each of Peterson et al., Reeck et al. and Kothari et al., Applicants argue in Paper No. 11 page 27 line 19 bridging to page 28, line 18, assert that the ECTHAM support binds due to an anion exchange mechanism, and is not pertinent to the instant charge switch mechanism.

As stated above, Reeck et al. teach the use of ECTHAM in a method involving the charge switch mechanism. The argument is therefore not found convincing.

26. In response to the rejection of claims 25-34 and 42-68 under 35 U.S.C. 103(a) as being obvious over Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al.,



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Hornes et al., Summerton et al., Tooley et al. and Cobbs et al., Applicants argue in Paper No. 11 page 29 and 30, assert that there is no motivation to combine the teachings of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al. and Summerton et al. with the teachings of Tooley et al. and Cobbs et al. because Tooley et al. and Cobbs et al. teach methods of ion exchange which is different from the charge switch method of the instant claims.

The method described in the claims has patentable weight only insofar as it pertains to the character of the solid phase product. The solid phase product of each of Peterson et al., Reeck et al., Kothari et al., the Sigma catalogue, Arnold, Jr. et al., Hornes et al., Summerton et al. has a unifying element which is the isolation of nucleic acids by a solid phase product which has ionizable groups bound to the surface. The motivation to combine references for the rejection of the claimed product does not have to be derived from the motivation provided by the instant claims or specification. The motivation to combine the references is clearly stated, and derived from the teachings of the cited references. Therefore, the argument is not found convincing.

### *New Grounds for Objection/Rejection*

#### *Claim Objections*

27. Claim 1-34 and 38-64 are objected to because of the following informalities: At independent claim 25, the US form of spelling is used in the claims, however, at claim 27 for

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instance, the British form of spelling is used for words such as "ionisable". For internal consistency, since the US form of spelling is used in the first appearing claim, the US form of spelling should be used throughout the claims set. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

28. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. Claims 25-34 and 42-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

30. Independent claims 25, 42, 51 and 59 (and therefore, all dependent claims) recite the limitation "a solid phase product" at the preamble, followed in the body of the claim by the phrases "the solid phase", and "the solid support". There appear to be distinctions between the meaning of "solid phase product" and "the solid phase", and "the solid support", since "solid phase product" seems to comprise the "solid phase", but there seems to be more components of the "solid phase product" than the "solid phase", and the "solid phase product" may also comprise the "solid support" which may be different from the "solid phase". Therefore, there is insufficient antecedent basis for the limitations "the solid phase" and "the solid support" the claims.

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31. Claim 34 recites at lines 5-9, "wherein the plurality of ionizable groups are (i) separately attached to a polymer (ii) polymerized, optionally by means of cross-linking reagents or (iii) separately attached to a polymer and polymerized, optionally by means of cross-linking reagents". This appears to be a group of conditions, (i), (ii) and (iii), which must be met by the water soluble product. However, because of the word "or" before (iii), this also appears to mean that some or all of items (i), (ii) and (iii) may be in the alternative. This being the case, it is not clear if all of the items (i), (ii) and (iii) are to be included in the water soluble product, one of the items (i), (ii) and (iii), or that the water soluble product may contain any combination of the items (i), (ii) and (iii). The claim is therefore vague and indefinite.

For the purposes of examination, the claim is interpreted to mean that each of items (i), (ii) and (iii) may be taken in the alternative.

32. Claim 63 recites the limitation "the polymer" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 102*

33. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published

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under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

34. Claims 25, 27, 28, 34, 42, 44 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,652,348 (Burton et al., of record).

Burton et al. teaches at the abstract, the summary, column 8, lines 18-33 and column 12, lines 26-52 a solid phase product which is water soluble, for use in a method of extracting nucleic acid from a sample, comprising a plurality of positively ionizable groups consisting of a polyamine or histidine. The ionizable groups are immobilized on a solid support by covalent bonds.

### *Conclusion*

35. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on December 18, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i).

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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37. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.  
Examiner  
March 19, 2003

  
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